This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92 and follows the Device Advice Guidance concerning "How To Prepare A Special 510(k)"

A. Submitter:

Submitter: Ameditech, Inc.
10340 Camino Santa Fe.
San Diego, CA 92121

Contact Person: Greg Cerra
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Date prepared: October 12, 2011

B. Device Names:

Ameditech ImmuTest Multi-Drug Screen Dipcard
Ameditech ImmuTest Multi-Drug Screen Cassette
Ameditech ImmuTest Multi-Drug Screen Cup

Predicates:

Ameditech ImmuTest Multi-Drug Screen Panel III (K050186)

C. Device Description:

The Ameditech ImmuTest Multi-Drug Screen is a lateral flow immunoassay intended for professional (prescription) use only. The device is used for the qualitative determination of parent compound and/or major metabolites of drugs in human urine specimens, and results are read visually. The device will be made available in three formats that use identical test strips: Dipcard, Cassette, and Cup. The modified device contains up to seventeen (17) assays that can include up to thirteen (13) different drugs at various cutoff concentrations. The assays detect different illicit drugs and medications that are commonly abused. Once the urine sample is administered, negative results can be read as soon as 1 minute and positive results should be read between 5 to 10 minutes. The presence of the line on the test region indicates a negative result for the drug and the absence of a line on the test region indicates a positive result for the drug. A visible line is also present at the control region of the test strip. This line should always appear, regardless of the presence of drugs or metabolites in the urine sample. This means that a negative urine sample will produce both a test line and control line, and a positive urine sample will generate only a control line. The presence of control line serves as a built-in control, which demonstrates that the test is performed properly.

D. Intended Use:

The ImmuTest Multi-Drug Screen is a one-step immunoassay for the qualitative detection of multiple drugs and drug metabolites in human urine at the following cutoff concentrations:

Test	Calibrator	Cut-off (ng/ml)
AMP	d-Amphetamine	1000
BAR	Secobarbital	300
BUP	Buprenorphine	10
BZO	Oxazepam	300
COC 150	Benzoylecgonine	150
COC	Benzoylecgonine	300
MDMA	3,4-methylenedioxymethamphetamine	500
MET 500	d-Methamphetamine	500
MET	d-Methamphetamine	1000
MTD	dl-Methadone	300
OPI 300	Morphine	300
OPI	Morphine	2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor-Δ9-THC-9-COOH	50

The ImmuTest Multi-Drug Screen consists of three test formats: card, cassette and cup. The configurations of the ImmuTest Multi-Drug Screen consist of any combination of the drugs listed above. The ImmuTest Multi-Drug Screen is used to obtain a visual, qualitative result and is intended for professional use only.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography/Mass Spectrometry (LC/MS) are the preferred confirmation methods.

E. Comparison with the Predicate

The modified device is identical to the cleared predicates referenced above (K050186). The drug strips cleared by FDA in submissions K040092, K042975, and K063015 will be consolidated into a single device. The purpose of this submission is to cover all the drug strips and their respective cutoffs with a single 510(k) clearance. See Section 12.2 of this submission for a detailed comparison of the modified device with the predicates.

F. Nonclinical Data:

As the test strips in both the modified and predicate devices are identical in terms of intended use, test principle, manufacturing process, and raw materials; simplified performance studies were conducted to demonstrate that the sensitivity, precision, and specificity of the modified device was unchanged from the predicate devices. The analytical performance verification and validation testing confirms that the Ameditech ImmuTest Multi-Drug Screen has equivalent performance compared with the predicate devices in terms of precision (reproducibility), analytical sensitivity, analytical specificity, and interfering substances.

G. Clinical Data:

Both the modified and predicate devices use identical test strips, therefore we did not conduct any clinical studies for this special 510(k) submission, because the performance characteristics that were validated in the predicate submissions are applicable to the modified device.

H. Conclusions Drawn from Testing Results:

Performance verification and validation studies have demonstrated that the device is as safe, as effective, and performs as well or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ameditech, Inc.
c/o Mr. Greg Cerra
Senior Manager, Regulatory Affairs
10340 Camino Santa FE, Suite F
San Diego, California 92121

NOV 10 2011

Re: k113046
Trade Name: Ameditech Immutest Milti-Drug Screen
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system.
Regulatory Class II
Product Codes: DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, LFG, LCM, JXN, LAF
Dated: October 13, 2011
Received: October 13, 2011

Dear Mr. Cerra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): k113046

Device Name: ImmuTest Multi-Drug Screen

Indications for Use:

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Prescription Use___X___ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801, Subpart D) (Part 21 CFR 807, Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

510(k): k113046